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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,482

02/07/2007

Thomas E. Lane

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EXAMINER

WEN, SHARON X

ART UNIT

PAPER NUMBER

1644

NOTIFICATION DATE

DELIVERY MODE

11/12/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SIP\_Docket@mwe.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,482	<b>Applicant(s)</b> LANE ET AL.	
	<b>Examiner</b> SHARON WEN	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 27-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Applicant's amendment, filed 07/07/2009, has been entered.  
Claims 1-45 are pending.  
Claims 27-45 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention/species, there being no allowable generic or linking claim.  
Claims 1-26 are currently under examination as they read on a method for reducing ocular inflammation comprising administering an agent that neutralizes CXCL10 wherein the agent reads on an CXCL10 antibody.
2. This Action will be in response to Applicant's Arguments/Remarks, filed 07/07/2009.  
The rejections of record can be found in the previous Office Action, mailed 01/07/2009.
3. The previous rejection under 35 U.S.C. 112, second paragraph, has been withdrawn in view of Applicant's amendment, filed 07/07/2009.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:  

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 1-26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Su et al. (*Journal of Virology* 1996, 70:1277-1281, reference of record) in view of Liu et al. (*Journal of Immunology* 2001, 167:4091-4097, reference of record).

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Applicant's argument has been fully considered but has not been found convincing for reasons of record and reiterated herein for Applicant's convenience.

The present claims are drawn to a method for reducing ocular inflammation comprising administering an agent that neutralizes CXCL10. Su et al. taught a method of treating ocular inflammation in subject with HSV-1 infection comprising administering a monoclonal antibody interocularly to mouse model of HSV-1 infection (see entire document, in particular, see page 1278, left column).

In particular, Su et al. taught a method to reduce ocular inflammation by reducing chemokine expression associated with HSV infection wherein CXCL-10 (aka. IP-10) was one the chemokines expressed during the infection (see page 1279, Figure 2 and last paragraph of left column).

Su et al. did not teach using an agent that specifically neutralizes CXCL-10 to reduce chemokine expression for treating ocular inflammation. However it would have been obvious to one of ordinary skill in the art, at the time of the invention was made, to use a neutralizing antibody specific for CXCL-10 because it was well known in the art that such anti-CXCL-10 antibody can neutralize CXCL-10 and reduce inflammation in other viral infected subjects as evidenced by Liu et al (see entire document, including Abstract and Discussion). In particular, Liu taught a neutralizing antibody to CXCL10 reduced the inflammation in a viral mouse model (see Results on pages 4093-4095).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to use an anti-CXCL10 neutralizing antibody as taught by Liu et al to reduce ocular inflammation in subjects with herpes virus infection as taught by Su et al.

The rationale to support a conclusion that the claims would have been obvious is that all the claimed elements (e.g, reducing ocular inflammation in herpes virus infection / neutralizing antibody to CXCL10) were known in the prior art and one skilled in the art could have arrived at the claimed invention by using known methods (administering said neutralizing antibody to reduce ocular inflammation in herpes virus infection) with no change in their respective functions and the combination would have yielded nothing more than predictable results of reducing for reducing ocular inflammation comprising administering an agent that neutralizes CXCL10.

Furthermore, the rationale to support a conclusion that the claims would have been obvious is that a particular known technique (administering a monoclonal antibody interocularly to reduce ocular inflammation in a subject with herpes virus infection) was recognized as part of the ordinary capabilities of one skilled in the art. One of ordinary skill in the art would have been capable of applying this known technique to a known product (e.g. neutralizing anti-CXCL10 antibody) that was ready for improvement and the results would have been predictable to one of ordinary skill in the art.

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Although the teachings by Su and Liu were limited to mouse model, it would have been obvious to one of ordinary skill in the art to extrapolate the data from the mouse model to human therapy with reasonable expectation of success because of that a person of ordinary skill had good reason to pursue the known options (e.g. administration a monoclonal antibody interocularly to reduce ocular inflammation in a subject with herpes virus infection / reducing inflammation with a neutralizing antibody for CXCL10). This leads to the anticipated success of reducing for reducing ocular inflammation comprising administering an agent that neutralizes CXCL10. It is likely the product not of innovation but of ordinary skill and common sense.

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

Given the combined teachings of Su and Liu rendered obvious of reducing ocular inflammation in a herpes infection, the same or nearly the same method would necessarily reduce the spread of the virus from cornea to retina or iris.

Given the above discussion, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant argues that Su et al. taught that antibody therapy did not involve IP-10 (aka. CXCL10) thus taught away from IP-10 as a neutralization target for reducing ocular inflammation. In response, the following is noted:

Su et al. first taught using chemokine profiling to looking for potential neutralizing target in the paragraph bridging pages 1277 and 1278, then taught IP-10 as one of the chemokines expressed during in vivo disease progression (see Figure 2). Although the treatment of anti-gD monoclonal antibody did not reduce the level of IP-10 (see Figure 3), Su et al did not conclude that IP-10 was not involved in the inflammation caused by HSV. Given that IP-10 was one of the chemokines found to be expressed during disease stage, one of ordinary skill in the art would be reasonably expected to target IP-10 in an attempt to reduce inflammation given the motivation taught by Su et al.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to use an anti-CXCL10 neutralizing antibody as taught by Liu et al to reduce ocular inflammation in subjects with herpes virus infection as taught by Su et al.

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Applicant's arguments have not been persuasive.

Therefore, the rejection of record is **maintained** for the reasons of record, as it applies to the amended claims. The rejection of record is incorporated by reference herein, as if reiterated in full.

### ***Conclusion***

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/

Examiner, Art Unit 1644

November 1, 2009

/Phillip Gambel/

Primary Examiner

Technology Center 1600

Art Unit 1644

November 5, 2009